

TITLE: VA Central IRB Convened Meeting Preparation**1.0 PURPOSE**

This standard operating procedure sets forth the policies and procedures the VA Central IRB administrative staff and VA Central IRB members follow when preparing for a convened meeting of the VA Central IRB. It also provides a framework to ensure that all VA Central IRB meetings are conducted in a professional manner and accurately documented in compliance with VA and other requirements.

2.0 REVISION HISTORY

Date of Initial Approval	May 27, 2008
Revision Dates	August 5, 2009 September 24, 2009 March 23, 2010

3.0 SCOPE

This Standard Operating Procedure applies to all VA Central IRB members and administrative staff who are involved in the scheduling of meetings, preparation of the agenda, communication with VA Central IRB members, distribution of project materials for review, and the conduct and documentation of the VA Central IRB meetings.

4.0 POLICY

4.1 It is the policy of the VA Central IRB that VA Central IRB members have adequate time for performing a thorough assessment of each proposed project, and that the documentation the members receive to perform the review is complete, accurate, and comprehensive enough to allow for such an assessment.

4.2 Applications are not scheduled for review by the convened VA Central IRB until the VA Central IRB Coordinator determines that the investigator provided all necessary materials in accordance with VA Central IRB SOP 104 or that they will be supplied by the investigator in sufficient time for members to review them.

4.3 All project documentation received from investigators and local sites is considered confidential and stored in a secure manner with limited access. This includes all project documentation generated by the VA Central IRB members as a result of their review of projects. All electronic data are kept secure in accordance with VA information security requirements, including the paper copies kept on file in the VA Central IRB Administrative Office and databases, as well as all copies distributed or forwarded electronically to VA Central IRB members for review.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 Primary Reviewer - The Primary Reviewer is a voting member of the VA Central IRB who has expertise in the area of the particular research project to be reviewed and is assigned by one of the VA Central IRB Co-Chairs to perform an in-depth review of a project, including the scientific methodology, in order to determine if the project is scientifically and ethically sound. The Primary Reviewer documents the results of his or her review on required checklists and leads the discussion of the project at the convened VA Central IRB meeting, presenting any issues and making recommendations regarding approval and/or modifications.

6.2 Secondary Reviewer - The Secondary Reviewer is a scientific voting member of the VA Central IRB and is responsible for conducting an in-depth review of an assigned project to determine if it is scientifically and ethically sound. The Secondary Reviewer also documents the results of his or her review on the required checklists and supplements the presentation and recommendations made by the Primary Reviewer at the VA Central IRB meeting, making recommendations as deemed necessary.

6.3 Informed Consent Reviewer - The Informed Consent Reviewer is a scientific or non-scientific voting member of the VA Central IRB responsible for conducting an in-depth review of the informed consent process, including the informed consent form; how the informed consent is given and obtained; and the process of documenting the informed consent for an assigned research project. The Informed Consent Reviewer also determines if the informed consent process meets all VA and other requirements for the participant population. The informed consent reviewer documents the results of the review on the required checklist and presents them, along with any recommendations regarding approval and/or modifications of the consent form and overall process, at the convened meeting of the VA Central IRB. When possible, the Informed Consent Reviewer remains the reviewer through out the study to include continuing review or when amendments and changes are made to the Informed Consent document.

6.4 Privacy Officer Representative – The Privacy Officer Representative is a non-voting member who reviews all projects submitted to the VA Central IRB, focusing on issues associated with the protection of participant privacy, to include review of any submitted HIPAA authorizations and/or Requests for Waiver or Alteration of HIPAA Authorization (VA Central IRB Form 103). The Privacy Officer Representative must sign off on the required certification form for each project reviewed by the VA Central IRB to ensure the project meets VA and other federal privacy and confidentiality requirements.

6.5 Information Security Officer (ISO) Representative – The ISO Representative is a non-voting member who reviews all projects submitted to the IRB to ensure they meet all VA information security requirements. The ISO must sign off on the required certification that each new project reviewed by the VA Central IRB to ensure the project meets VA requirements for information security.

6.6 All other VA Central IRB members who are not serving as a reviewer on a project that is being reviewed at a convened meeting are responsible for reviewing the project documents received in their agenda package and for being prepared to discuss any questions or issues they may have with the research project and the informed consent process during the convened meeting.

6.7 The VA Central IRB Co-Chairs are responsible for the following:

- Working with the VA Central IRB Administrator in assigning VA Central IRB voting members as reviewers for specific research projects in accordance with the member's expertise as well as prior and current workload.
- Identifying the need for ad hoc consultants.
- Assisting in the scheduling of meetings and for designating the Co-Chair responsible for overseeing the review of specific studies and signing the VA Central IRB decision documents for those projects
- Performing, in conjunction with the designated reviewers, review functions for all submitted actions for a project submitted or referred to the convened IRB for review.
- Conducting the meeting in accordance with the agenda, ensuring that all studies receive a thorough review and that all members have had the opportunity to voice their opinions, while still ensuring that business is conducted in an efficient and timely manner.

6.8 The VA Central IRB Coordinators are responsible for ensuring all project documents and applicable checklists and certification forms have been completed and that items for review are added appropriately to the agenda and the materials prepared and uploaded to SharePoint and/or distributed to reviewers and other VA Central IRB members in a timely and accurate manner. They also prepare the draft agenda tools for their assigned projects.

6.9 The VA Central IRB Administrator is responsible for preparing the meeting agenda, scheduling meetings at dates and times a quorum, to include one of the Co-Chairs, is available, and for ensuring agenda packages are available to the all members, to include both voting and non-voting members, in timely manner so they have sufficient time to perform a thorough review of all materials. The VA Central IRB Administrator also ensures that applicable training topics are included in the agenda or training materials or documents distributed as needed.

7.0 PROCEDURES

7.1 Meeting Chair. The two VA Central IRB Co-Chairs co-chair all meetings in which both are in attendance, with one Co-Chair designated the Presiding Co-Chair for the purpose of facilitating the meeting agenda and for reviewing and signing the meeting minutes. The Co-Chairs will alternate the responsibility for serving as the Chair for specific projects to be reviewed, or work out a system of project assignment compatible with their individual knowledge and experience concerning the projects. Each Co-Chair keeps the VA Central IRB Administrator informed concerning His or her availability to conduct VA Central IRB business and promptly notifies the other Co-Chair and the VA Central IRB Administrator if he or she cannot oversee the conduct of a meeting or review of a project as scheduled. At least one of the Co-Chairs must be in attendance in person or via audio or video conference, or the meeting will be re-scheduled.

7.2 Scheduling of VA Central IRB Meetings and Member Attendance. Meetings are scheduled to be held every month. A calendar of meeting dates is established at least six months to a year in advance and published on the VA Central IRB website, along with the associated project application deadlines.

7.2.1 In general, meetings are scheduled for the third or fourth Friday of the month but the date and time may change based on the availability of the Co-Chairs and members.

7.2.1.1 Additional meetings via audio and/or video conference may also be scheduled as needed between the scheduled monthly meetings to take action on time sensitive issues.

7.2.1.2 If no actions are pending review, a regularly scheduled meeting may be cancelled. If only a few actions are pending that do not merit the time and expense of an in-person meeting, a meeting can be convened via audio or video teleconferencing as long as quorum requirements are maintained, all members attending the meeting had sufficient time to review all materials to be reviewed, and all members are able to be heard and actively participate.

7.2.2 The VA Central IRB administrative staff sends out a notice to all members approximately three weeks prior to the scheduled meeting date to remind members to inform the VA Central IRB Administrative Office of their availability to attend the next regularly scheduled meeting. Further information concerning the submission of travel cost estimates by the members, the provision of travel authorizations, making hotel reservations, and submitting expense reports for travel to and from the meetings can be found in VA Central IRB Administrative SOP 200, VA Central IRB Meeting Logistics.

7.2.2.1 Members who cannot attend a scheduled meeting must notify the VA Central IRB Administrative Office as far in advance as possible so the VA

Central IRB Administrator can ascertain whether a meeting that complies with regulatory requirements for a quorum will be met for that meeting.

7.2.2.2 The VA Central IRB Administrator makes every effort to obtain a quorum for a scheduled meeting date by contacting all available members, assisting them in making audio and video conferencing arrangements as necessary, and advising on travel arrangements if required. If a quorum cannot be attained, the meeting will be rescheduled as soon as possible.

7.3 Assignment of Reviewers. Upon receipt of a submitted new project application, the VA Central IRB Administrator, in consultation with at least one of the Co-Chairs, assigns Primary and Secondary reviewers.

7.3.1 The VA Central IRB Administrator keeps a list of all voting members' areas of expertise and works with a Co-Chair to assign voting members to be Primary and Secondary Reviewers, to each new project scheduled to be reviewed at a convened IRB meeting. Assignments are based on the reviewer's scientific or scholarly expertise in relation to each project. The number of reviews already conducted by each voting member is also taken into consideration if more than one member has the required expertise in order to facilitate a balanced workload among the members.

7.3.2 Assigned reviewers are contacted as to their availability to perform the designated review and whether they may have any potential conflicts of interest. If they are not available or have a potential conflict, another reviewer is assigned.

7.3.3 Once Primary and Secondary reviewers are assigned and confirmed for a new project, they may continue to perform review functions for all submitted actions for that project to include continuing reviews, requests for amendments or modifications, and review of serious adverse events and unanticipated problems involving risks to participants or others, as well as protocol deviations, that are referred for convened IRB review.

7.3.3.1 When situations arise where a Reviewer cannot perform a review on a certain action, such as if the Reviewer resigns from the VA Central IRB; the Reviewer's appointment term expires and is not renewed; or the member is unable to perform the review due to workload or other commitments, one of the Co-Chairs appoints another voting member to be the Reviewer or one of the Co-Chairs will assume the Reviewer's role for ongoing projects.

7.3.3.2 If the Primary Reviewer cannot be in attendance but can perform the review, he or she can submit comments in writing to the VA Central IRB in advance of the meeting for consideration. The Secondary Reviewer can brief the VA Central IRB on the Primary Reviewer comments and provide additional comments as applicable.

7.3.4 If it is determined that an ad hoc consultant is needed, the Presiding Co-Chair for that project consults with the VA Central IRB Administrator and the Director, PRIDE, as needed, on recruiting a suitable candidate who can perform the review in time for the scheduled meeting. A Primary Reviewer, Secondary Reviewer, and an Informed Consent Reviewer, if applicable, will still be appointed from the voting VA Central IRB membership.

7.3.4.1 Ad hoc consultants submit a written report of their findings by completing the applicable VA Central IRB Reviewer Checklist. The checklist can be supplemented by an additional written report if desired by the ad hoc consultant. The completed checklist and/or written comments is made available or distributed to the VA Central IRB members prior to the scheduled meeting.

7.3.4.2 If the Presiding Co-Chair requests review of only a certain portion or part of the project, the ad hoc consultant does not complete the reviewer checklist but submits a written report addressing only the assigned issues. These comments will be distributed as indicated in paragraph 7.3.4.1.

7.3.4.3 At the discretion of the Presiding Co-Chair, the ad hoc consultant may attend the meeting to present his or her findings and answer any questions but will not cast a vote.

7.3.5 The VA Central IRB Administrator also assigns an Informed Consent Reviewer at the same time as the Primary and Secondary Reviewers are assigned if applicable. An Informed Consent Reviewer is assigned if the project involves obtaining informed consent from a participant, even if there is a request for waiver of documentation of informed consent. An Informed Consent Reviewer will not be assigned if there is a request for waiver of informed consent. Any voting member of the VA Central IRB may serve in this capacity. The VA Central IRB Administrator will assign a non-scientist for this review, if practical, but may also assign a scientific member in an effort to ensure that the workload of the various members is as balanced as possible.

7.4 Agenda Preparation. The VA Central IRB Administrator prepares a draft agenda for each convened meeting as follows:

7.4.1 The agenda is constructed following the order of business in the meeting template sample found in VA Central IRB SOP 115, Preparation and Distribution of VA Central IRB Meeting Minutes.

7.4.2 The VA Central IRB Administrator ensures that all projects that were approved under the expedited review process since the previous meeting, as well as all projects that were exempted from review, are also listed on the agenda or referenced on the main agenda and a detailed listing attached. In addition, other actions that were reviewed using expedited procedures, such as review of minor amendments, protocol deviations, approval of Local Site Investigator Applications, review of minor

modifications or local site comments, and reports of serious adverse events or unanticipated problems involving risks to subjects or others, will also be listed. At a minimum, the agenda or agenda attachment will contain the following minimum information for each expedited review action or exemption approved:

- Name of each project, to include VA Central IRB number and ORD funding service number project number if applicable
- Name of Principal Investigator/Study Chair or Local Site Investigator as applicable
- Type of action that was approved, i.e., continuing review, new project or a minor modification to previously approved research
- Date of approval
- Exemption or expedited review category for new studies

7.4.3 At a minimum, the agenda will contain the following information for each project action to be reviewed at the convened meeting:

- Name of each project, to include VA Central IRB number and ORD funding service number if applicable
- Name of Principal Investigator/Study Chair
- Local Site Investigator and Site for reviews of Local Site Investigator Applications or other local site actions
- Names of Reviewers
- Type of action to be reviewed

7.4.4 The VA Central IRB Administrator will tentatively allot an amount of time to each item listed on the agenda based on the type of action being reviewed. If there are too many items that have been submitted for review to fit into a regular meeting agenda in the time allowed, the VA Central IRB Administrator will consult the VA Central IRB Co-Chairs and schedule an additional meeting by phone or video conference that will take place approximately five working days or more after the regularly scheduled convened meeting. Separate agendas will then be drafted for each meeting. Items that require review by the convened Board, but that are not as complex as others, are moved to the additional meeting agenda as much as possible to make room on the regular meeting agenda for sufficient discussion of any complex issues.

7.4.5 The VA Central IRB Administrator will also include educational items on the agenda for the VA Central IRB members as needed and time permits. Educational materials will be included in the agenda packages made available to members.

7.5 Reviewer Checklists. The VA Central IRB Coordinator for each project pending review prepares applicable reviewer checklists for completion by all reviewers assigned to a project. The VA Central IRB Coordinators fill in the first section of each

checklist identifying the project, investigator, and the reviewer assignment. These checklists are included in the agenda package or a separate study package and forwarded to the reviewers as soon as the reviewer assignments are made. This can be done through the use of SharePoint or encrypted e-mail.

7.5.1 For new projects to be reviewed by the convened VA Central IRB, the following is required:

7.5.1.1 Both the Primary and Secondary Reviewers are required to complete the VA Central IRB Form 111a, Reviewer Checklist for PI/SC New Project Application (Attachment 1), and/or the VA Central IRB Form 111b, Reviewer Checklist for Local Site Investigator Applications (Attachment 2) as applicable for the particular review being performed.

7.5.1.2 For Principal Investigator/Study Chair New Project Applications to be reviewed by the convened IRB that involve obtaining informed consent, the Informed Consent Reviewer is required to complete a VA Central IRB Form 113, Reviewer Checklist for Informed Consent (Attachment 3). The Primary and Secondary Reviewers also receive a copy of VA Central IRB Form 113 to complete, if applicable, for the project to be reviewed.

7.5.1.3 For the review of comments submitted by local sites representatives in response to the VA Central IRB's initial review of a PI/SC New Project Application, the VA Central IRB Coordinator compiles all the comments and highlights specific comments that require review by the convened IRB. Other comments that do not require review by the convened IRB, such as routine administrative questions, are answered by the assigned VA Central IRB Coordinator and copies of the responses provided to the VA Central IRB for informational purposes or further action if required by the convened IRB.

7.5.2 For review of new Local Site Investigator Applications, the VA Central IRB Form 113 does not have to be completed. The VA Central IRB Coordinator for that project completes a comparison table of the informed consent document, and other documents if applicable, such as the HIPAA authorization and recruitment materials, against the approved model documents to determine if there are any changes not reported by the investigator. These comparison results are included as part of the agenda package for the convened meeting.

7.5.3 For requests for continuing review, the Primary reviewer for that project is required to complete the VA Central IRB Form 114a, Continuing Review Checklist for Local Site Investigator Applications (Attachment 4) and the VA Central IRB Form 114b, Reviewer Checklist for Continuing Review (PI/SC Application) (Attachment 5).

7.5.3.1 If the workload for a particular project is significant, such as if a project has a large number of Local Site Investigator Applications for review, the

Primary Reviewer can request that the Secondary Reviewer assist in the review. The Secondary Reviewer would then consult with the Primary Reviewer regarding the review of the PI Application and complete checklists for those sites assigned to the Secondary Reviewer for review.

7.5.3.2 The VA Central IRB Coordinator for that project also completes a comparison of the informed consent document and other documents, if applicable, against the currently approved documents to determine if there are any changes not reported by the investigator. These results are included as part of the agenda package for the convened meeting, as well as a listing of the documents being provided for review.

7.5.4 For requests to amend an already approved project, only the Primary Reviewer is required to complete the VA Central IRB Form 120, Reviewer Checklist for Amendments (Attachment 6).

7.5.4.1 If the amendment involves only minor changes to an informed consent document, the Primary Reviewer and Informed Consent Reviewer do not need to complete a VA Central IRB Form 113, Reviewer Checklist for Informed Consent. If there is a substantive change to the informed consent document or process affecting one or more of the basic or additional required elements of informed consent, the VA Central IRB Form 113 must then be completed by both the Primary and Informed Consent Reviewers.

7.5.4.2 If an amendment is submitted as part of a continuing review report, a separate VA Central IRB Form 120 does not need to be completed by the reviewer for the amendment.

7.5.5 If an assigned reviewer realizes that he or she has a conflict of interest with an assigned project after receiving the checklist and project documents, the reviewer immediately notifies the VA Central IRB Coordinator and returns the reviewer checklist indicating that there is a conflict. The VA Central IRB Coordinator consults if necessary with the VA Central IRB Administrator regarding assignment of another reviewer and the Administrator updates the meeting agenda accordingly.

7.6 Preparation of Certification Forms. Both the Information Security Officer (ISO) Representative and the Privacy Officer Representative on the VA Central IRB must be provided a certification form for all new projects to be reviewed to document that they have reviewed the project and that it conforms to all VA information security and privacy requirements as applicable.

7.6.1 Each VA Central IRB Coordinator prepares a VA Central IRB Form 122, Information Security Officer (ISO) Compliance Review (Attachment 7) and a VA Central IRB Form 123, Privacy Officer Compliance Review (Attachment 8) for all new projects listed on the meeting agenda and includes them in the meeting agenda packages of the applicable representatives.

7.6.2 Upon receipt of the agenda package, each representative completes these forms as applicable. The representative can certify that all requirements are met or they can indicate on the form that his or her review is only an interim review. They can then provide comments that must be addressed by the investigator before providing a final certification. The certification forms and comments are then returned to the VA Central IRB Coordinator who makes them available to the VA Central IRB members at the convened meeting and/or uploads them into the SharePoint meeting site. The representatives may also turn them in at the VA Central IRB meeting if the representatives are present and available to brief the members on any issues identified.

7.7 Distribution of Project Materials. Approximately two weeks prior to a scheduled meeting, the agenda materials are made available on the secure SharePoint VA Central IRB site or sent via encrypted e-mail, fax, or express courier to all VA Central IRB members who indicated they could attend the meeting, either in person or via audio or video teleconferencing. A summary of the types of materials to be distributed can be found at attachment 9. Agenda packages will be prepared and distributed in accordance with VA Central IRB Administrative SOP 200.

7.7.1 For initial and/or re-review of new projects, all VA Central IRB members are provided access to the full project application package with the exception of any training certificates that may have been submitted. The review comments from local sites are also available if applicable. Reviewers also receive access to all applicable checklists and reviewer forms.

7.7.2 For requests for continuing review, materials are distributed and/or made available on the SharePoint meeting folder for the applicable month as follows:

7.7.2.1 The following materials are provided to all members:

- The continuing review report forms from both the PI/SC and each of the Local Site Investigators, and any associated forms or reports, such as local audit reports or DSMB/DMC reports.
- The comparison tables developed by the VA Central IRB Coordinator for the local site documents that are based on approved PI/SC model documents and currently approved local documents.
- The current approved model informed consent document and model HIPAA authorization if applicable.
- The currently approved PI/SC New Project Application

7.7.2.2 The Primary and Secondary Reviewers are provided access to all of the above documents, the applicable continuing review checklists, and a copy of the entire approved project file, to include the protocol or grant application. All current approved Local Site Investigator Applications will also be made available. These documents will be uploaded in a designed Reviewer subfolder under the SharePoint

meeting folder. Other members may also access this folder if they wish to view these documents.

7.7.3 For review of amendments to previously approved research that are being reviewed at a convened meeting, whether in conjunction with a continuing review report or as a separate action, materials are distributed and/or made available as follows:

7.7.3.1 All VA Central IRB members have access to copies of all modified documents, as well as the originals of those documents for comparison. Documents with tracked changes may also be available.

7.7.3.2 For review of new Local Site Investigator applications the following materials are available:

- VA Central IRB Form 104, Local Site Investigator Application and all associated documents submitted with the package.
- Comparison table to the PI/SC Application as prepared by the VA Central IRB Coordinator
- Copy of approved VA Central IRB 108, PI/SC New Project Application.
- A copy of the specific model documents when the local documents differ other than local site contact information

7.7.4 For review of other actions such as serious adverse events or unanticipated problems involving risks to subjects or others; protocol deviations and violations; and complaints and/or reports of noncompliance, guidance for document distribution can be found in the applicable SOPs covering these issues.

7.8 Receipt of Agenda Packages by Members and Review of Materials. Prior to beginning review of their materials, each member should review the handout, "Member Pre-Meeting Protocol Review Instructions," (Attachment 10) which is included in the agenda package.

7.8.1 Upon receipt of the agenda packages, each member is expected to check the documents received against the meeting agenda to ensure that all are present. If documents are missing, members should immediately contact the VA Central IRB Administrator.

7.8.2 The names of the Primary or Secondary reviewers are not shared with investigators by the VA Central IRB administrative staff or other members unless a reviewer agrees that his or her name can be released or the Reviewer releases his or her own name.

7.8.3 Upon review of their assigned projects, reviewers may contact investigators directly concerning any questions or to request additional information or clarification.

7.8.3.1 If the reviewers elect to do this, they must notify the VA Central IRB Coordinator for that project and provide a copy of any written request (e-mail, letter, and fax) or a written summary of any phone conversation. If the VA Central IRB Coordinator is not copied on the written investigator response, the reviewer must provide a copy to the Coordinator or upload it under the SharePoint Reviewer subfolder. This documentation will be included in the project file by the VA Central IRB Coordinator.

7.8.3.2 If reviewers do not wish to contact the investigator directly, they can forward a list of questions to the VA Central IRB Coordinator, who then contacts the investigator for a response.

7.8.4 Once the response is received from the investigator, the VA Central IRB Coordinator ensures the reviewers receive copies, if applicable, and that a copy is provided to all VA Central IRB members who will be attending the meeting. The copies will be provided either at the convened meeting or prior to the meeting via fax, express delivery, encrypted e-mail, or the documents will be uploaded into the SharePoint meeting folder. A copy is also filed in the project folder.

7.8.5 Upon completion of their review, all reviewers provide a copy of the completed reviewer checklists to the VA Central IRB Coordinator. This can be done prior to or after the convened meeting.

7.9 Preparation of Agenda Tools. Each VA Central IRB Coordinator will prepare an agenda tool for each assigned project. This tool contains all required determinations that must be made by the convened VA Central IRB for each project and serves as an aide for documenting the VA Central IRB's determinations and requested modifications. A sample of the agenda tool can be found at Attachment 11.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.5 VHA Directive 2007-040, Appointment of Information Security Officer (ISO) and Privacy Officer to the Institutional Review Board (IRB) or the Research and Development (R&D) Committee

11 Attachments

1. VA Central IRB Form 111a, Reviewer Checklist for PI New Project Application
2. VA Central IRB Form 111b, Reviewer Checklist for Local Site Investigator Applications
3. VA Central IRB Form 114a, Reviewer Checklist for Continuing Review (PI/SC Application)
4. VA Central IRB Form 114b, Continuing Review Checklist for Local Site Investigator Applications
5. VA Central IRB Form 113, Reviewer Checklist for Informed Consent
6. VA Central IRB Form 120, Reviewer Checklist for Amendments
7. VA Central IRB Form 122, Information Security Officer Compliance Review
8. VA Central IRB Form 123, Privacy Officer Compliance Review
9. VA Central IRB Project Review Action Package Contents
10. Member Pre-Meeting Project Review Instructions
11. Sample Project Agenda Tool

I have reviewed and approved the contents of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Reviewer Checklist for PI/SC New Project Application



Project and Reviewer Identification (To be completed by VA Central IRB Coordinator)

VA Central IRB Number	
Title of Project	
Type of Review	<input type="checkbox"/> Expedited <input type="checkbox"/> Full Board
Principal Investigator/Study Chair	
Reviewer	
Review Assignment	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Ad Hoc If the assigned reviewer has a Conflict of Interest, do not proceed. Go to Section 14 and check the applicable box.

Section 1: Principal Investigator General Information

	YES	NO	N/A
1. Does the Principal Investigator appear to have adequate expertise to conduct the project as described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Has the Principal Investigator certified that the VA required training for all study team members is up-to-date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Based on the Principal Investigator's current research activities, does the Principal Investigator appear to have sufficient time and resources to oversee this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. If the Principal Investigator or any of the other study team members has a conflict of interest, is there an adequate plan to eliminate it or manage it appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If there are Co-Principal Investigators, are the applicable VA Central IRB Forms 108a included in the package and does the Co-Investigators meet all of the above requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are there any state and local laws that have been identified which conflict with federal or VA requirements or which need to be considered prior to making an approval decision?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 2: Project Overview

<i>The Reviewer may also attach a separate summary of the project that is used to brief Board members during a convened meeting.</i>		YES	NO	N/A
1.	Is the non-technical project summary written in terms a lay person could understand?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Is the purpose of the project clearly and concisely stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Is adequate justification provided to conduct the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Is the project design scientifically sound?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Whenever possible, does the project utilize procedures that minimize risk to research participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Will observations and measurements be made during the project and are they clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If the project involves the use of questionnaires, survey instruments, or telephone scripts, are any concerns with the contents of those tools adequately addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. If the project uses such methods as control groups, placebo, or deception, is their use adequately justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there an adequate summary of the methods of statistical analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is there a clear identification of which procedures are standard of care versus being done solely for research purposes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the project plan include adequate follow-up care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. If a participant withdraws for any reason, will the participant have appropriate follow-up care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Is the overall project design in the protocol consistent with the information provided by the Principal Investigator on the VA Central IRB Form 108, Principal Investigator New Project Application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Is the overall project design adequate to achieve the project objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 3: Potential Risk/Benefits Analysis

	YES	NO	N/A
1. Are all the potential risks stated clearly (e.g., physical, psychological, financial, social, or legal?)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are risks minimized by making use of procedures already being performed on the participants for diagnostic or treatment purposes or by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are risks reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that might reasonably be expected to be gained from completion of the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. If the project involves more than minimal risk, does the project include a data safety monitoring plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If the project does involve a data safety monitoring plan, is it adequate to ensure the safety of the participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Has the Principal Investigator included an adequate, detailed plan concerning how information and communication will be managed among participating sites for such things as project modifications, interim results, adverse events and unanticipated problems, and if applicable, data safety monitoring?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the participant's medical record need to be flagged to protect the participant's safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Does the level of risk require continuing reviews that are more frequent than annually? If so, please indicate recommended level below. Recommended Frequency:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. What is the risk level of the project? <input type="checkbox"/> Minimal Risk <input type="checkbox"/> Greater than Minimal Risk			

10. What are the potential benefits to the participants?
<input type="checkbox"/> Direct <input type="checkbox"/> Indirect <input type="checkbox"/> Both <input type="checkbox"/> None
Comments:

Section 4: Human Participant Information

	YES	NO	N/A
1. Is the number of participants to be enrolled and the duration of their participation appropriate for the purposes of the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If non-Veterans are included as part of the target population, is their inclusion justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the selection of human participants equitable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the population targeted appropriate for the proposed research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there a vulnerable or other special population involved in the research? If yes, the following additional questions must be answered.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Has the use of the vulnerable population or other special population been adequately justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is the appropriate VA Central IRB Form 110, Vulnerable Population Supplement, included as part of the application if applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Are the additional safeguards in the project sufficient to ensure the participants are adequately protected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Is there an adequate plan to protect the participants from undue influence or coercion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is there an adequate plan to protect the privacy interests of the participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the use of human participants in the research have scientific relevance and embody the principles of the Belmont Report (Justice, Respect for Persons, and Beneficence)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 5: Informed Consent

	YES	NO	N/A
1. Will informed consent be sought from each prospective participant? <i>If no, skip to question 5 in this section.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the model informed consent provided by the Principal Investigator contain all required elements and any additional elements based on the type of project being submitted? <i>See note at end of this section.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is consent from a Legally Authorized Representative (LAR) being sought? If yes, the following additional questions must be answered.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Is consent being obtained from a health care agent appointed by the participant in a legal document, a court-appointed guardian, or the next-of-kin per applicable state law?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Will an appropriate medical evaluation be made by the practitioner, in consultation with the Chief of Service or Chief of Staff, that the prospective research participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time and will this be documented in the medical record in a signed and dated progress note?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. When the determination that a prospective research participant lacks decision making capacity is based on a diagnosis of mental illness, will a consultation with a psychiatrist or licensed psychologist be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Will all disclosures that are required to be made to the participant, be made to the participant's LAR?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. For minors and/or participants with impaired decision making capacity, is an assent process included if appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Are there provisions to give the LAR a description of the proposed research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Is the LAR told that their obligation is to determine what the participant would do if the participant was competent, or if the participant's wishes cannot be determined, what the LAR thinks is in the best interests of the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Does the Principal Investigator have an adequate plan for training Local Site Investigators on informed consent procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If informed consent is not being sought, is there a VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process, included with the application and adequate justification provided ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If a waiver of informed consent is being sought for recruitment purposes only, is there a VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process included with the application and adequate justification provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If a request for waiver of documentation of informed consent is being requested is VA Central IRB Form 112b, Request for Waiver of Documentation of Informed Consent, included with the project application and is adequate justification provided based on the project parameters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			
<p>Note: The reviewer must also complete VA Central IRB Form 113, Informed Consent Reviewer Checklist, and attach it to this checklist to complete this section. The reviewer will not be expected to present the model consent form at the meeting but should be prepared to supplement the Informed Consent Reviewer's comments as appropriate.</p>			

Section 6: HIPAA Authorization for Project Participants

The Privacy Officer Representative of the Board will also review the study to determine compliance with HIPAA.	YES	NO	N/A
1. Is a HIPAA authorization required and included as part of the application package and does it conform to the protocol and the informed consent document?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If a waiver of HIPAA authorization is being requested, is VA Central IRB form 103 included in the application and does the waiver request meet all the required waiver approval requirements as detailed on the form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 7: Participant Recruitment Information

	YES	NO	N/A
1. Is a standard recruitment strategy clearly indicated by the investigator and is it appropriate for the targeted populations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are copies of model recruitment materials (e.g., include telephone scripts, ads, brochures, letters, etc.) <i>that are to be used for recruitment</i> provided? <i>If yes, the following additional questions must be answered. If no model recruitment materials are going to be used, skip to Section 8.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are the provided model recruitment materials an appropriate means of communication for the populations to be recruited?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do recruitment and/or advertising materials clearly state that the project involves research and if using an investigational product, do the advertisements clearly state that the product is investigational?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is the condition under study or the purpose of the research clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is time or other commitments that will be required of potential participants clearly indicated, as well as the location where the research will take place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is a brief list of procedures to be performed included?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is a clear summary of inclusion/exclusion criteria provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are points of contact for further information about the project prominently displayed (e.g., name, address, and phone number of the Principal Investigator or space for local site project personnel contact information to be displayed?)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Are the recruitment materials free of any unfounded claims, to include any claims of "free" treatment; exculpatory language, or unjustifiable suggested benefits for project participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Do the recruitment materials contain contact information for the veteran to verify that the study is a valid VA study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. If payment is being provided, is the information provided regarding the payment and the amount not overemphasized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. If the study includes an FDA-regulated product, are the advertisements consistent with the product labeling?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 8: Payments to Participants

	YES	NO	N/A
1. Will participants be paid for their participation? <i>If yes, the following additional questions must be answered. If no, skip to section 9.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the payment reasonable, commensurate with the subject's participation, and not coercive in nature in relation to the amount, method, and timing of the payment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the payment strategy clearly indicated by the investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the payment pro-rated as the study progresses and is any "bonus" or completion payment not so large as to unduly influence the participant to stay in the study until completion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is the payment strategy appropriate for the population being targeted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. If the study is intended to enhance the diagnosis or treatment of the medical condition for which the participant is being treated, does the investigator provide information, does the investigator provide information that it is standard of practice in non-VA institutions to provide such payment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If transportation costs are being reimbursed, are these costs incurred outside the participant's normal course of treatment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 9: Biological Specimens

	YES	NO	N/A
1. Will biological specimens be collected as part of this project? <i>If yes, the following questions must be answered. If no, skip to section 10.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are any specimens collected going to be "banked" for future research purposes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the investigator applying to a tissue bank for use of tissues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are the specimens to be stored only in VA-sponsored (under VA ownership and control) or VA-approved (approved by the Chief, Research and Development Officer) tissue banks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If the investigator is banking the specimens, is there a plan for keeping a copy of the original consent under which each specimen was collected, a record of the use of the specimens, and a listing of all the projects under which the specimens will be used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If specimens are to be analyzed at a non-VA institution, is there a written understanding between the VA investigator and the non-VA institution that specifies the analysis/use as defined in the project and that any remaining quantities are returned to the VA or destroyed in a certified manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If data generated from the specimens is linked with the clinical data by code, is the linkage only performed by VA investigators within the VA?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. If data is not coded or linked, is only the information to be shared devoid of any unique identifiers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. If the specimens are to be de-identified, are these procedures adequate to ensure participant anonymity and are they in accordance with HIPAA and the Common Rule?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is the investigator taking sufficient and appropriate measures to minimize the potential harm from breaches of confidentiality and privacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Is there an adequate plan for destruction of the specimens?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 10: Privacy and Confidentiality

	YES	NO	N/A
1. Does the investigator adequately explain how the project team will access information from or about the participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the investigator adequately explain how the participant's identifiable private information will be handled, stored and disseminated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are there adequate provisions to protect the privacy of the participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Are there adequate provisions to maintain the confidentiality of the identifiable data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. In the project design for the recruitment process, will the researcher make initial contact with participants in person or by letter prior to any telephone contact and then refer to those prior contacts when telephoning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Does the investigator have a Certificate of Confidentiality or is the investigator in the process of applying for one?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If an investigator does not have a Certificate of Confidentiality, should the investigator apply for one?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Will names, addresses, and social security numbers (real or scrambled) be replaced with a code and will documentation of the procedure by which the data was coded remain within the VA only?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is who has access to the code and who holds the code clearly spelled out in the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is there an appropriate plan for project closure and the retention of the project files and data for at least five years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Is there a plan for the ultimate destruction of the identifiable data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the investigator provide sufficient information regarding the project's compliance with VA information security policies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 11: FDA-Regulated and Other Products

	YES	NO	N/A
1. Are FDA-regulated drugs or devices used in this project? <i>If yes, the following additional questions must be answered. If no, skip to section 12.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the source of the drug or device clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has a copy of an FDA letter been received stating wither receipt of the IND application or approval of an IDE application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. If an IND/IDE number is provided, does it match the project or correspondence supplied in the rest of the project materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is the name of the IND or IDE holder specified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If the investigator is claiming an IND or IDE exemption, does the project comply with the requirements at 21 CFR 312.2(b) for drug exemptions and 21 CFR 812.2(c) for device exemptions)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If an investigational brochure has been provided, do the risks described in the informed consent document adequately reflect the risks described in the brochure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the plan for drug or device accountability adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. For investigational drugs, if a model VA Form 10-9012, Investigational Drug Information Record is provided, is it consistent with the informed consent document?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If this is a non-significant risk device study, is there an explanation stating why the device is not a significant risk device and is it accurate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 12: Local Site Investigator and Local Participating Site Information

	YES	NO	N/A
Does the number and mix of local sites identified by the Principal Investigator seem adequate and appropriate for the recruitment of the required populations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 13: Criteria for Approval of Research

All of the following must be checked "Yes" or N/A if applicable, in order to recommend approval or approval with minor modifications.	YES	NO	N/A
1. Are the risks to the subjects minimized by:			
(1) Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk	<input type="checkbox"/>	<input type="checkbox"/>	
(2) Using procedures already being performed on the subjects for diagnostic or treatment purposes whenever appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	
2. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is the selection of subjects equitable?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Will informed consent be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 38 CFR 16.116?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Will informed consent be appropriately documented, in accordance with and to the extent required by 38 CFR 16.117?	<input type="checkbox"/>	<input type="checkbox"/>	
6. When appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, are additional safeguards included in the study to protect the rights and welfare of these subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Have all real or potential conflicts of interest been managed, reduced, or eliminated?	<input type="checkbox"/>	<input type="checkbox"/>	
10. Have the investigators listed on the PI Application met all required educational requirements for the protection of human subjects and are they qualified to conduct the research?	<input type="checkbox"/>	<input type="checkbox"/>	

Section 14: Reviewer Recommendation

The reviewer must check one of the boxes below and return a copy to the VA Central IRB Administrative Office prior to the scheduled meeting at which the project will be reviewed or turn in a copy at the meeting.

<input type="checkbox"/>	I have a conflict of interest and am returning this checklist without review.
<input type="checkbox"/>	I recommend approval of this project. Any comments below are suggestions only.
<input type="checkbox"/>	I recommend approval of this project pending minor modifications as stated below or attached.
<input type="checkbox"/>	This project can only be approved after major modifications have been made as stated in below or attached and the project is reviewed again at a full meeting of the IRB to ensure all required modifications are satisfactory. <i>(To be used only if project is going to be reviewed by convened Board).</i>
<input type="checkbox"/>	I do not recommend approval of the project for the reasons indicated in Section 14. <i>(To be used only if project is going to be reviewed by the convened Board.)</i>
<input type="checkbox"/>	Deferred for review by the convened IRB. <i>(To be used only in the expedited review process – Please specify deferral reason below.)</i>

Do participant medical records need to be flagged to protect the safety and welfare of the participant?

☐ Yes ☐ No

Requested Modifications or Deferral Reasons as applicable: *(May be continued on a separate piece of paper)*

Reviewer Signature

Date

This section is for use during the Expedited Review Process only.

Section 15: VA Central IRB Co-Chair Final Approval

The VA Central IRB Co-Chair makes one of the following final approval decisions:

<input type="checkbox"/>	Approved Awaiting Local Context Reviews. <i>(For use with newly submitted projects only)</i>
<input type="checkbox"/>	Approved. No further changes are necessary.
<input type="checkbox"/>	Modifications Required for Approval. Required modifications are detailed by reviewer are required with any additional modifications or comments indicated below.
<input type="checkbox"/>	Defer for Review by the Convened Board. Reasons for Deferral are indicated below.

Required Modifications for Reasons for Deferral:

Signature of Co-Chair

Date

Reviewer Checklist for Local Site Investigator Applications



Project and Reviewer Information (To be completed by VA Central IRB Coordinator)

VA Central IRB Number				
Title of Project				
Principal Investigator				
Reviewer				
Reviewer Assignment	<input type="checkbox"/> Primary	<input type="checkbox"/> Secondary	<input type="checkbox"/> Ad Hoc	Specialty: _____

This checklist is used by the Reviewers in reviewing all the VA Central IRB Forms 104, Local Site Investigator Applications, for multi-site projects. If there have been any changes to the model documents as approved in the PI Application, these will be noted by VA Central IRB administrative staff and the reviewers will need to review and comment on the identified changes.

This form lists multiple sites on one form. If there are more sites than there is room on the form, additional checklists are provided. Reviewers should place a "check mark" for each site next to the checklist item if the item is met and an "x" in the box for that site if the checklist item is not met. If an item is Not Applicable, Reviewers should place an "N" in the appropriate box.

This is checklist _____ of _____
(To be completed by VA Central IRB Coordinator)

Reviewer Checklist for Local Site Investigator (LSI) Applications

Checklist Items					
Section 1 LSI General Information					
1. The LSI has adequate expertise to conduct the project as described.					
2. Based on the LSI's current research activities, the LSI appears to have sufficient time and resources to oversee the project at this site.					
3. Neither the LSI, nor any of the local project team, has a conflict of interest or, if one has been identified, there is an adequate plan to eliminate or manage it.					
Comments:					
Section 2 Project Overview					
1. The site has affirmed that it has the resources available to treat emergencies resulting from project-related procedures.					
2. State and local laws that may impact on the deliberations of the VA Central IRB are identified.					
3. Any ethnic, religious, or other special characteristics of the community or other local issues that need to be considered by the VA Central IRB in reviewing the project are identified.					
4. Other committee reports that need to be considered by the VA Central IRB in their review of the project such as Biosafety or Radiation Safety are identified and are or will be provided.					
Comments:					

Checklist Items					
Section 3 Local Site Potential Risk Benefits Analysis					
1. The potential risk/benefits analysis as described by the LSI for their site does not differ from that given by the PI.					
2. If medical records are to be flagged, the method for doing this is documented.					
Comments:					
Section 4 Local Site Human Participant Information					
1. The site has affirmed that it can meet its enrollment goals.					
2. There are no non-veterans to be recruited, or if there are, their use at the site is permitted because there are insufficient numbers of veterans available to complete the project.					
3. The selection of human participants at this site is equitable.					
4. If vulnerable populations are to be enrolled at this site, additional safeguards are in place to protect the participant's health and welfare.					
5. Does the investigator have an adequate plan to protect the privacy rights of the participant?					
Comments:					
Section 5 Local Site Informed Consent					
1. Informed consent will be obtained at this site.					
2. There is an adequate plan for training local site project team members on obtaining informed consent.					
3. The plan allows participants sufficient opportunity or time to consider whether or not to consent.					
4. Steps have been taken at this site to minimize undue influence and/or coercion.					

Checklist Items		I		
5. If this site is obtaining informed consent from someone other than the participant, there are criteria in place for determining which individuals meet the requirements for being a legally authorized representative.				
6. If assent is not being obtained from participants who cannot give informed consent, there is adequate justification for not doing so.				
7. If some or all participants have impaired decision making capacity at this site, there is an adequate plan in place to determine their capacity to consent.				
8. If non-English speaking participants are consented at this site, there is an adequate translation of the consent document and a plan in place for conducting the discussion in a language understandable to the participant, or the parents or LARs of the participants as applicable, for ongoing communication with the participant throughout the project, and during emergencies.				
9. Other than local point of contact information, the model informed consent document has not been further modified by the LSI.				
Comments:				
Section 6 Local Site HIPAA Authorization The site has not made any changes to the model HIPAA Authorization other than site demographics and point of contact information.				
Section 7 Local Site Participant Recruitment Information				
1. The Local Site Investigator has a clear recruitment strategy, and it is appropriate for the targeted populations.				
2. The Local Site Investigator has an adequate plan for training personnel who will be obtaining informed consent.				

Checklist Items				
3. If the local site investigator is not using the standard recruitment materials provided by the Principal Investigator, modified recruitment materials are provided for review.				
4. If modified documents are provided, they meet all the following criteria:				
a. The materials are an appropriate means of communication for the populations recruited.				
b. The materials clearly state the project involves research.				
c. The purpose of the research is clearly stated.				
d. Time or other commitments required of participants is clearly stated.				
e. A brief list of procedures to be performed is included.				
f. There is a clear summary of inclusion/exclusion criteria.				
g. Points of contact for further information are prominently displayed, to include a contact number for the participant to verify the validity of the study.				
h. The materials do not make unfounded claims or unjustifiably suggest benefits for participants.				
Comments:				
Section 8 Local Site Payment to Participants				
1. If the payment plan for this site differs from that described by the Principal Investigator, the method, reason, and schedule of payments is detailed.				
2. The payment plan is reasonable and not coercive.				
Comments:				

Checklist Items					
Section 9 Biological Specimens					
1. If specimens are to be banked, procedures for de-identifying the specimens, if different from that described by the PI, are detailed and are in accordance with all HIPAA and Common Rule requirements.					
2. Measures taken to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy are described.					
3. If tissue is to be banked and the banking procedures differ from those described by the PI, the differences are described.					
Comments:					
Section 10 Privacy and Confidentiality					
1. If the site is coding identifiable information, the person maintaining the code is identified and the storage site within VA is identified.					
2. If data are not coded, any information shared outside the VA is devoid of all unique identifiers.					
3. The plan for transferring any data to the PI and/or the Coordinating Center is adequate.					
4. The plan for storing the data on-site is adequate.					
5. The plan for protecting all research data from improper use and disclosure is adequate.					
Comments:					

Checklist Items				
Section 11 FDA-Regulated and Other Products				
1. If FDA-Regulated and other products are used at this site, the drugs and devices are clearly specified and, for drug studies, a local VA Form 10-9012 is provided describing local drug stability and storage requirements.				
2. The plan for storage, monitoring and dispensing of the drugs or devices is compliant with VA policy.				
Comments:				

Reviewer Recommendation

The reviewer should check one of the following recommendations regarding approval of the above sites to participate in this research project:
<input type="checkbox"/> All of the above sites are suitable as participating sites for this project and meet all IRB approval criteria. No changes need to be made.
<input type="checkbox"/> All of the above sites are suitable as participating sites for this project and meet all IRB approval criteria. However, the below listed sites need to make minor modifications to the Local Site Investigator Application as specified:
<input type="checkbox"/> All of the above sites are suitable as participating sites for this project. However, the below listed sites need to make major modifications to the Local Site Investigator Application as specified.
<input type="checkbox"/> All of the above sites are suitable as participating sites for this project and meet all IRB approval criteria with the exception of the following:
Reason site is not suitable:

Reviewer Checklist for Continuing Review (PI/SC Application)



VA Institutional Review Board for Multisite Studies

Project and Reviewer Identification (To be completed by VA Central IRB Coordinator)

VA Central IRB Number			
Title of Project			
Type of Review	<input type="checkbox"/> Expedited <input type="checkbox"/> Convened Board		
Principal Investigator/Study Chair			
Current Approval Interval		Expiration Date:	
Current Risk Level	<input type="checkbox"/> No more than minimal risk <input type="checkbox"/> Greater than minimal risk		
Reviewer			
Review Assignment	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Ad Hoc If the assigned reviewer has a Conflict of Interest, do not proceed. <input type="checkbox"/> Check this box and return this form to the VA Central IRB Coordinator for this study.		

Section 1: Principal Investigator/Study Chair General Information

	YES	NO	N/A
1. Has there been any change in the status of the Principal Investigator/Study Chair or PI/SC study team (e.g., additions or removal) since the most recent approval of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Has new information been received since the most recent IRB approval of the project that changes the Principal Investigator/Study Chair's expertise to conduct or complete the project?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Are there any potential conflicts of interest that have been identified and submitted with this Continuing Review application by the PI/SC? <i>Note: If potential conflicts of interest have been submitted with the Continuing Review application, a copy of the determinations made by the local facility must also be included.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments:			

Section 2: Continuing Review Issues

	YES	NO	N/A
1. Has participant enrollment exceeded the number of participants approved for this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Have any participant recruitment issues or complaints been submitted by the PI/SC that require additional action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Have there been any DSMB reports submitted with this Continuing Review application or since the last approval of this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, are there issues within the DSMB reports that require additional action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	

4. Have there been SAEs, unanticipated problems, or adverse events submitted since the last approval of this project?	<input type="checkbox"/>	<input type="checkbox"/>	
If yes, are there issues within these reports that require additional action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Has any new information been received since the last approval of this project requiring additional action by the VA Central IRB that impacts the potential risks or benefits associated with this study or the willingness of participants to enroll or continue in the research?	<input type="checkbox"/>	<input type="checkbox"/>	
Comments:			

Section 3: Informed Consent and HIPAA Authorization Issues

	YES	NO	N/A
1. Is the PI/SC requesting changes in the informed consent process or documentation of HIPAA authorization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If changes have been requested, are the changes appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
If changes are appropriate, is reconsenting or notification of previously enrolled and/or currently enrolled participants required?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Are there additional revisions to the informed consent document or HIPAA authorization required because of changes in policy or applicable requirements (e.g., record retention language in the informed consent and HIPAA authorization)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 4: Evaluation of Additional Information Submitted by PI/SC

	YES	NO	N/A
1. Is the PI/SC requesting approval of modifications or amendments with this continuing review application?	<input type="checkbox"/>	<input type="checkbox"/>	
If so, is approval of the requested modifications or amendments appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Did the PI/SC report any preliminary observations, interim findings not included in a DSMB report, literature, or other information about presentations or publications applicable to the approved project requiring action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is there any other supplemental material in the PI/SC's continuing review application (e.g., audits, correspondence from sponsor) not previously referenced requiring action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	
Comments:			

Section 5: Summary of Issues After Review of Local Site Investigator Applications

	YES	NO	N/A
1. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in the reasons participants withdrew from the approved project requiring action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in reported protocol deviations or violations requiring action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in reported unanticipated problems involving risks to subjects or others or adverse events requiring action by the VA Central IRB?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there new information reported in a Local Site Investigator Continuing Review Application (e.g., RCO audits) that requires action by the VA Central IRB for the PI/SC and/or all participating site investigators and coordinating centers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you recommend independent verification (e.g., audit) of this project to ensure that no material changes have occurred? If so, indicate why in the comments section below.	<input type="checkbox"/>	<input type="checkbox"/>	
Comments:			

Section 6: IRB Approval Criteria

The following are the IRB Approval Criteria. Please check whether each criterion is still met for continued approval.	YES	NO	N/A
1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	<input type="checkbox"/>	<input type="checkbox"/>	
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.	<input type="checkbox"/>	<input type="checkbox"/>	
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special issues in research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.	<input type="checkbox"/>	<input type="checkbox"/>	

<p>4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §16.116.</p> <p><i>Note: §16.116 is the Common Rule requirements for general requirements of informed consent, including the requirement to provide each subject with the basic elements of informed consent as well as additional elements of informed consent as determined by the IRB. This section of the Common Rule allows an IRB to waive or alter the basic elements of informed consent or waive the requirement to obtain informed consent if specific requirements are met.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §16.117.</p> <p><i>Note: §16.117 is the Common Rule requirements for documentation of informed consent. Informed consent must be documented through the use of a written consent form approved by the IRB and signed and dated by the applicable individuals as described in VHA Handbook 1200.05 unless the IRB determines specific requirements are met to approve a waiver of documentation of informed consent.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>Comments:</p>			

Section 7: Reviewer Recommendation or Decision (for Studies Undergoing Expedited Review)

Please check a box under each heading as indicated.

The Continuing Review Frequency (check one):

- ☐ 12 months ☐ 6 months ☐ Other:

Level of Risk (check one):

- ☐ Minimal Risk ☐ Greater than Minimal Risk

Please indicate one of the following:

For projects to be reviewed at a convened Board meeting:

- ☐ Approval recommended to the convened IRB with no modifications.
- ☐ Approval recommended to the convened IRB after minor modifications as described below are approved.
- ☐ Table. Major modifications are required as described below requiring additional review of responses by the convened IRB.
- ☐ Suspend or Terminate.

For projects undergoing expedited review

- ☐ Approve by expedited review category . No modifications required.
- ☐ Modifications required for approval.
- ☐ Suspend
- ☐ Project submitted for expedited review, but defer for continuing review by the convened IRB.

Required Modifications or Reasons for Deferral/Suspension/or Termination (please list below):

Reviewer Signature

Date

Continuing Review Checklist for Local Site Investigator Applications



Project and Reviewer Information (To be completed by VA Central IRB Coordinator)

VA Central IRB Number			
Title of Project			
Principal Investigator			
Reviewer			
Reviewer Assignment and Process	<input type="checkbox"/> Primary <small>If the assigned reviewer has a Conflict of Interest, do not proceed. <input type="checkbox"/> Check this box and return this form to the VA Central IRB Coordinator</small>	<input type="checkbox"/> Secondary <input type="checkbox"/> Ad Hoc	<input type="checkbox"/> Convened Board <input type="checkbox"/> Expedited Review

This checklist is used by the Reviewers in reviewing all the VA Central IRB Forms 115a, Local Site Investigator Applications, for multi-site projects. If there have been any changes to the local site informed consent document, HIPAA authorization, recruitment materials, or other associated documents, these will be noted by VA Central IRB administrative staff and the reviewers will need to review and comment on the identified changes.

This form lists multiple sites on one form. If there are more sites than there is room on the form, additional checklists are provided. Reviewers should place a "Y" for Yes or an "N" for No for each checklist item. If an item is not applicable, please place a "NA" for the checklist item.

This is checklist _____ of _____
 (To be completed by VA Central IRB Coordinator)

Continuing Review Checklist for Local Site Investigator (LSI) Applications

Checklist Items: Y = Yes; N = No; NA = Not Applicable	[Site A]	[Site B]	[Site C]	[Site D]	[Site E]	[Site F]	[Site G]
Section 1 LSI General Information							
1. There has been no change in the status of the LSI or LSI/study team (e.g., additions or removal) since the most recent approval of the project.							
2. No information has been received since the most recent IRB approval of the project that changes the LSI's expertise to conduct or complete the project.							
3. No potential conflicts of interest have been identified and submitted with the Continuing Review application.							
Comments:							
Section 2 Continuing Review Issues							
1. Participant enrollment has not exceeded the number of participants approved at the local site.							
2. No new participant recruitment issues or complaints have been submitted by the LSI requiring additional action by the VA Central IRB.							
3. No issues based on review of the enrollment information submitted by the LSI require additional action by the VA Central IRB.							
4. No SAEs, unanticipated problems, or adverse events have been submitted by the LSI requiring additional action by the VA Central IRB.							
5. No new information that impacts the potential risks or benefits associated with the study or the willingness of participants to enroll or continue in the research has been received from the LSI requiring additional action by the IRB.							
6. The progress reported at this site does not require additional verification from anyone other than the Local Site Investigator.							

Checklist Items: Y = Yes; N = No; NA = Not Applicable	[Site A]	[Site B]	[Site C]	[Site D]	[Site E]	[Site F]	[Site G]
Comments: (for Continuing Review Issues)							
Informed Consent and HIPAA Authorization Issues							
1. Changes have been requested by the LSI in the informed consent process or HIPAA authorization.							
A. If changes have been requested, the changes are appropriate.							
B. If changes are appropriate, reconsenting or notification of previously enrolled and/or currently enrolled participants is required.							
2. No revisions to the LSI's informed consent or HIPAA authorization are required because of changes in policy or applicable requirements (e.g., record retention language in the informed consent and HIPAA authorization).							
3. An informed consent or regulatory audit conducted by the RCO or equivalent since the last approval period has identified issues requiring additional action by the VA Central IRB.							
Comments:							

Checklist Items: Y = Yes; N = No; NA = Not Applicable	[Site A]	[Site B]	[Site C]	[Site D]	[Site E]	[Site F]	[Site G]
Evaluation of Additional Information Submitted by LSI							
1. The LSI has requested approval of a modification specific to the participating site other than an informed consent or HIPAA authorization modification (e.g., advertisement) that requires additional action by the VA Central IRB.							
2. The LSI has reported information specific to the participating site that requires additional action by the VA Central IRB.							
Comments:							
IRB Approval Criteria							
<i>The IRB Approval Criteria are included on the last page of this Review Checklist and should be used as a reference when answering the following question for each site.</i>							
All of the IRB approval criteria continue to be met.							
Comments:							

Reviewer Recommendations or Decision: Y = Yes; N = No	[Site A]	[Site B]	[Site C]	[Site D]	[Site E]	[Site F]	[Site G]
1. Approve with no modifications.							
2. Modifications required to obtain approval as described.							
3. Suspend the study at the participating site.							
4. Terminate the study at the participating site.							

**Required Modifications (please list below and indicate
(a) whether the modification is minor or major, and
(b) which site(s) the modification applies:**

Reviewer Signature _____ Date _____

IRB Approval Criteria

1.	Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2.	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3.	Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special issues of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4.	<p>Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §16.116.</p> <p><i>Note: §16.116 is the Common Rule requirements for general requirements of informed consent, including the requirement to provide each subject with the basic elements of informed consent as well as additional elements of informed consent as determined by the IRB. This section of the Common Rule allows an IRB to waive or alter the basic elements or informed consent or waive the requirement to obtain informed consent if specific requirements are met.</i></p>
5.	<p>Informed consent will be appropriately documented, in accordance with, and to the extent required by §16.117.</p> <p><i>Note: §16.117 are the Common Rule requirements for documentation of informed consent. Informed consent must be documented through the use of a written consent form approved by the IRB and signed and dated by the applicable individuals as described in VHA Handbook 1200.05 unless the IRB determines specific requirements are met to approve a waiver of documentation of informed consent.</i></p>
6.	When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7.	When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8.	When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Reviewer Checklist for Informed Consent



I. (To be completed by VA Central IRB Coordinator)

VA Central IRB Number	
Title of Project	
Principal Investigator	
Reviewer	<div style="text-align: right;">Initial Review <input type="checkbox"/> Continuing Review <input type="checkbox"/></div> <p>If the assigned reviewer has a Conflict of Interest, do not proceed. Go to Section IV and check the applicable box.</p>

II. (To be completed by Reviewer)

Required Elements	YES	NO	N/A
1. Is there a statement indicating that the project involves research?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is there an explanation of the purposes of the research?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is the duration of the participant's expected participation stated?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Is there a detailed chronological description of the procedures to be followed?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Are procedures that are being done solely for the purposes of the research identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Are procedures which are experimental identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
7. Is the participant advised of any reasonably foreseeable risks or discomfort that may occur as a result of their participation?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Are participants advised that there is also the possibility of unknown risks?	<input type="checkbox"/>	<input type="checkbox"/>	
9. Is there a description of any potential benefits to the participant or to others that may reasonably be expected from the research?	<input type="checkbox"/>	<input type="checkbox"/>	
10. If there is no direct benefit to the participant, is this clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	
11. Are appropriate alternative treatments or procedures that may be advantageous to the participant disclosed or if there are none, is this so stated?	<input type="checkbox"/>	<input type="checkbox"/>	
12. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained?	<input type="checkbox"/>	<input type="checkbox"/>	
13. Is there a detailed description of the procedures that will be followed to ensure adequate privacy and security?	<input type="checkbox"/>	<input type="checkbox"/>	
14. For research involving more than minimal risk, is there a description of what compensation may be available if an injury occurs as a result of the research to include where further information may be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Are points of contact provided for the participant to contact for answers to questions about the research, research participant's rights, and in the event of a research-related injury to the participant?	<input type="checkbox"/>	<input type="checkbox"/>	

16. Is at least one of the points of contact someone other than the investigator or project team members whom the potential participant can contact to verify the validity of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
17. Is there a statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant is otherwise entitled?	<input type="checkbox"/>	<input type="checkbox"/>	
18. Is there a statement that a veteran participant will not be required to pay for care in a VA research project except for any applicable co-payments unrelated to the research project?	<input type="checkbox"/>	<input type="checkbox"/>	
19. Does the informed consent document accurately convey the project procedures described in the project documents?	<input type="checkbox"/>	<input type="checkbox"/>	

II. (To be completed by Reviewer)

Additional Elements (These must be included if applicable)	YES	NO	N/A
1. Is there a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo, fetus, or nursing infant) if the participant becomes pregnant during the course of the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the responsibilities of the participant regarding his/her participation spelled out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are any anticipated circumstances under which a participant's participation may be terminated by the investigator without the participant's consent explained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are there any additional costs to the participant that may result from his/her participation in the research and are these spelled out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are participants being offered payment for their participation? If payment is being offered the following questions must be answered.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Is the payment reasonable and non-coercive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is there a description of how payment is to be made?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Are there provisions included for pro-rating the payment if a participant's participation is terminated prior to completion of the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are the consequences of a participant's decision to withdraw from the project adequately explained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is there a description for the orderly termination of the participant's participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is there a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation, will be provided to the participant in a timely manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the approximate total number of participants involved in the project specified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. For projects involving genetic research, if a possible commercial product or test may be developed as a result of the research, is there a statement that the participant will not profit from any products or tests that might result from use of their sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. For research projects involving tissue banking, are all the following requirements detailed in the consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Is the participant allowed the choice of deciding if the specimen will be used for future research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is the participant informed whether any research results, based on re-use of their specimen, will be provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Is there a clear statement as to whether the participant will be re-contacted after the project is completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Is there a provision for the participant to request that all his/her	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

specimens and all links to the clinical data be destroyed if desired?			
12. If the investigator is receiving payment to conduct the research and/or has been mandated by the IRB or the Conflict of Interest Committee to disclose any conflicts of interest, is this stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Are appropriate HIPAA elements attached separately with the rest of the project documents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. If the participants are minors or have impaired decision-making capacity is the signature block for the participant's legally authorized representative included?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Is the form written in language understandable to the participants or the participant's legally authorized representative?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Has a readability score been provided that is between the 6 th and 8 th grade level or, in your opinion, is the readability level of the informed consent document acceptable for the population to be targeted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Is the informed consent document free of exculpatory language?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. If the participant does not read or write English, is an appropriate translation of the consent form provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

IV. (To be completed by Reviewer)

Administrative Requirements	YES	NO	N/A
1. Is the consent form properly formatted in accordance with the approved template, to include all required headers?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is medical jargon avoided and are any and all technical terms explained?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Does the consent form use the second person (you, your, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Is the potential participant clearly invited to participate and informed why he or she has been invited to participate?	<input type="checkbox"/>	<input type="checkbox"/>	
5. For research involving questionnaires, surveys, or interviews, does the consent form provide an adequate description of the types of questions that will be asked or topics that will be covered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. If a Certificate of Confidentiality is required for the project, does the consent form state this, as well as providing a description of the extra protection (and limitations to such protection) that is afforded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the potential subject given a chance to discuss the project with the investigator or other project team members and does it state that the participant will be given a copy of the consent form after signature?	<input type="checkbox"/>	<input type="checkbox"/>	
8. For amendments and continuing review applications, has the consent form been adequately modified to reflect current procedures or is it still reflective of current procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained and a detailed description of the procedures that will be followed to ensure adequate security?	<input type="checkbox"/>	<input type="checkbox"/>	

V. Comments and Recommendations (To be completed by the Reviewer)

The reviewer must make a comment or recommendation below for any checklist item that was marked "No" and specify the item number, i.e., II.3. Continuation sheets can be attached.

The reviewer may also attach a marked up copy of the informed consent form or any of the other project materials, i.e., advertisements, telephone scripts, etc., with any changes, edits, or suggested wording. The reviewer should assign one of the following codes for each change:

1 – Regulatory

3 – Editorial Simplification

5 – Missing Material

2 – Editorial Clarification

4 – Inconsistent with protocol

6- Suggested Wording

IV. (To be signed by Reviewer and turned into the VA Central IRB Administrative Office)

Reviewer Recommendation (Check one)

- ☐ I recommend approval of the informed consent document with no changes.
- ☐ I recommend approval of the informed consent document with the above recommended changes
- ☐ I do not recommend approval of the current informed consent document and suggest a total re-write be accomplished.
- ☐ I have a conflict of interest and am returning this form without making a determination.

Signature

Date

Reviewer Checklist for Amendments



VA Institutional Review Board for Multisite Studies

Project and Reviewer Identification *(To be completed by VA Central IRB Coordinator)*

VA Central IRB Number	
Title of Project	
Type of Review	<input type="checkbox"/> Expedited <input type="checkbox"/> Full Board
PI/SC or LSI Amendment	<input type="checkbox"/> PI/SC <input type="checkbox"/> LSI Site:
Amendment Number	
Reviewer	
Review Assignment	<input type="checkbox"/> Primary <input type="checkbox"/> Ad Hoc If the assigned reviewer has a Conflict of Interest, do not proceed. Check this box <input type="checkbox"/> and return this form to the VA Central IRB Coordinator for this study.

Section 1: Amendment Issues to be Considered

	YES	NO	N/A
1. Does the investigator give an adequate rationale for the changes requested in the proposed amendment?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Have all applicable documents been submitted with the changes incorporated to maintain consistency between the protocol, the VA Central IRB Application, and any informed consent or HIPAA authorization documents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Does this amendment result in any change in the risk/benefit ratio for participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Could these changes affect the willingness of participants to continue in the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there an adequate plan for informing the participant of these changes and re-consenting of participants if required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Does this change require a more frequent continuing review interval than is currently established for this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the study and/or study site still meet all IRB approval criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			

Section 2: Reviewer Recommendation (Convened Board) or Decision (Expedited Review)

Please check one of the boxes below in each of the headings as applicable:

Amendment Type

☐ Major ☐ Minor

Level of Risk (check one):

☐ Minimal Risk ☐ Greater than Minimal Risk

Recommendation or Decision

For amendments to be reviewed at a convened Board meeting:

- ☐ Approval with no modifications.
- ☐ Approval after minor modifications as described below are approved.
- ☐ Table. Major modifications are required as described below requiring additional review of responses by the convened IRB.
- ☐ Disapprove the amendment

For amendments undergoing expedited review

- ☐ No modifications required.
- ☐ Modifications required for approval.
- ☐ Project submitted for expedited review, but defer for review by the convened IRB.

Modifications or Reasons for disapproval or deferral:

Reviewer Signature

Date

Information Security Officer (ISO) Compliance Review



VA Institutional Review Board for Multisite Studies

This form is used by the Information Security Office Representative of the VA Central IRB to document their review of human subjects research in accordance with VHA Directive 2007-040.

☐

Interim Review

☐

Final Review

Section 1: Protocol Identification *(To be completed by VA Central IRB Coordinator)*

Title of Protocol:

VA Central IRB Number:

Principal Investigator:

Name of Reviewer:

Section 2: Documentation of Review *(To be completed by VA Central IRB Information Security Office Representative)*

The VA Central IRB Information Security Office Representative must check one of the below boxes.

☐ I certify that I have reviewed the above protocol. All policies and procedures described meet VA and other regulatory requirements for access, maintenance, transmission, and storage of sensitive research data to include the following:

- 1) The investigator adequately explains how information will be protected during transmission.
- 2) If information will be stored outside of the VA network, the investigator includes all required protections in the explanation of how the data is to be stored.
- 3) The investigator has indicated the appropriate knowledge of incident reporting procedures in the event information or equipment is lost, stolen, or misplaced.

☐ I certify that I have reviewed the above protocol. I have the following concerns regarding the policies and procedures described for the access, maintenance, transmission, and storage of sensitive research data.

Comments:

Signature

Date

Privacy Officer Compliance Review



This form is used by the Privacy Office Representative of the VA Central IRB to document their review of human participants research in accordance with VHA Directive 2007-040.

☐

Interim Review

☐

Final Review

Section 1: Protocol Identification *(To be completed by VA Central IRB Coordinator)*

Title of Protocol:

VA Central IRB Number:

Principal Investigator:

Name of Reviewer:

Section 2: Documentation of Review *(To be completed by VA Central IRB Privacy Officer Representative)*

The VA Central IRB Privacy Officer Representative must check one of the below boxes.

- ☐ I certify that I have reviewed the above project. All procedures described meet VA and other regulatory requirements for access, maintenance, and storage of protected health information.
- ☐ I certify that I have reviewed the above project. I have the following concerns regarding the procedures described for the access, maintenance, and storage of protected health information.

Comments:

Signature

Date

VA Central IRB Project Review Action Package Contents

PI/SC New Project Application

If applicable, study packets may include but are not limited to:

- VA Central IRB Form 108 (PI New Project Application)
- Protocol
- ORD funding Letter
- Biosketches of all listed investigators on PI/SC Application
- Local findings on COI for all listed study team members
- Model VA Research Informed Consent Form (VA Form 10-1086)
- Request for waiver or alteration of informed consent (VA Central IRB Form 112a)
- HRC Committee Meeting Minutes (CSP Studies Only)
- Prior Informed Consents (if is a follow-up study)
- HIPAA Authorization
- Request for waiver of HIPAA Authorization (VA Central IRB Form 103)
- Investigator's Drug Brochure
- Investigational Device Information (if applicable)
- Request for Waiver of Documentation of Informed Consent (VA Central IRB Form 112b)
- Vulnerable Population Supplement (VA Central IRB Form 110 Series)
- Model Recruitment Materials
- Model Participant's Instructions
- Model Questionnaires or Surveys
- Model Scripts
- Model VA Investigational Drug Information Record (VA Form 10-1092)
- Local site comments (30-day) if applicable

Local Site Investigator Application

If applicable, study packets may include but are not limited to:

- Copy of approved VA Central IRB 108
- VA Central IRB Form 104 (Local Site Investigator Application) and all applicable associated documents to include COI determinations, local investigator biosketches or CVs, and local documents based on model documents detailed under the PI/SC New Project Application Table
- Comparison Table of local site documents to model documents

Continuing Review Application

If applicable, study packets may include but are not limited to:

- Table of Documents Provided for Continuing Review
- VA Central IRB forms 115a and 115b as applicable
- Comparison Table of local site documents submitted to current, approved documents
- Most recently approved VA Central IRB Form 108 (PI/SC App)
- Copy of current Informed Consent Forms (Model and LSIs)
- Copy of current HIPAA Authorizations (Model and LSIs)
- DSMB/DMC reports as applicable
- Local audit reports (Regulatory, Informed Consent, Other)
- Amendment Requests submitted with 115a and/or 115bs

Modifications to Previously Approved Research

If applicable, study packets may include but are not limited to:

- VA Central IRB form 116
- Copies of all modified documents with tracked changes

Reviewers will receive copies of their applicable checklists and, for continuing reviews and amendments, copies or access to the entire file. Other members may be granted access to the entire file if they wish.

Updated: March 29, 2010

Member Pre-Meeting Project Review Instructions



The agenda and project review packages for the VA Central IRB meeting scheduled for the date and time indicated on the agenda are available on the SharePoint meeting site. If you are unable to attend this meeting, either in person or via audio or video conference, please immediately inform the VA Central IRB Administrator at 202-461-1813.

Instructions for all members

- ☒ A draft meeting agenda and all the project materials that will be reviewed at the upcoming VA Central IRB meeting are available on the SharePoint site. If you cannot access the site, please call the VA Central IRB Administrator immediately at 202-461-1813.
- ☒ Please review the agenda to determine if you have been assigned as a primary, secondary, or an informed consent reviewer for the purposes of presenting the project at the meeting. If you have, please also reference the additional instructions for these assignments.
- ☒ As a VA Central IRB member, you are required to review all materials prior to the meeting in sufficient depth to discuss the information at the convened meeting and make an informed decision on whether to approve the research.
- ☒ A VA Central IRB Form 127, Conflict of Interest Declaration (VA Central IRB members) is also being provided. **This must be turned in at the meeting or, if you are participating via audio or teleconference, faxed to 202-254-0162 or sent by encrypted e-mail the Meeting Coordinator prior to the meeting.**
- ☒ All project documents, whether in paper or electronic form, must be kept in a secure manner in accordance with VA requirements for maintenance of sensitive information. Hard copy documents can be turned into the VA Central IRB staff after the meeting to be shredded.
- ☒ For further guidance, members should consult the VA Central IRB Administrative staff or review the VA Central IRB SOPs on the VA Central IRB website at <http://www.research.va.gov/programs/pride/cirb/default.cfm>.

See next page for additional instructions for assigned reviewers, and the Privacy Officer and Information Security Officer representatives.

Instructions for Assigned Reviewers

- ☑ Reviewer assignments are indicated on the agenda. The applicable reviewer checklist has been included in your package for each project for which you are assigned as a reviewer. The project identification and reviewer assignment part of the checklist has already been completed for you.
- ☑ If you have a conflict of interest concerning a protocol to which you have been assigned, please immediately notify the VA Central IRB Coordinator.
- ☑ Use the checklists to conduct your review. Complete the checklists and turn them into the VA Central IRB Coordinator prior to or at the meeting.
- ☑ All reviewers, to include the ISO and Privacy Officer, may contact the PI in advance of the meeting if they have any questions. A copy of this correspondence or a summary of the telephone contact must be forwarded to the VA Central IRB Coordinator. Reviewers may also contact the VA Central IRB Coordinator with their questions for the investigator and the Coordinator will contact the Investigator to obtain a response. This is highly recommended in order to resolve or clarify issues prior to the meeting.

Reviewer Roles

Reviewers should use their applicable checklists as a tool and brief the Board on all IRB approval criteria and any required modifications.

- ☑ Primary Reviewers should be prepared to lead the discussion of their assigned projects during the meeting and to make recommendations. They will be expected to brief the rest of the members concerning the scientific and ethical issues of the research in regard to the use of human subjects and the mandated federal IRB approval criteria. The Primary Reviewer will be expected to make a motion regarding the approval of the project after it has been discussed at the convened meeting.
- ☑ Secondary Reviewers will supplement the Primary Reviewer based on their own in-depth review of the project and should also be prepared to discuss concerns and make recommendations.
- ☑ Primary and Secondary Reviewers for new projects must also complete the Informed Consent Reviewer Checklist but will not be expected to lead the discussion on informed consent for the assigned project, although they should give input as needed.
- ☑ The Informed Consent Reviewer for an assigned project will lead the discussion concerning the content of the informed consent form to include determining whether it contains all required elements, and recommending any modifications.
- ☑ For the Information Security Officer (ISO) and Privacy Officer members, the applicable review certification forms have been uploaded to SharePoint. This must be completed and turned in prior to or at the meeting.

VA Central IRB Meeting Agenda Tool

{Date}

Regular Business – {Start Time}

Check Off

1. Attendance Taken (Phone and Quorum verified)	
2. Conflict of Interest Statement by Chair and Turn-in of COI forms	
3. Review of Meeting Minutes of {Meeting Date}	
4. Report of Expedited Items Reviewed and Approved	

Review of PI Application for {VA Central IRB #, Title, PI} – {Start Time}

Overview	
1. Primary and Secondary Reviewer Overview	
2. Discussion of Issues—{List time of Investigator Call-in}	
3. Risk Level <input type="checkbox"/> Minimal Risk or <input type="checkbox"/> Greater than Minimal	
PI/SC Application Package {List as Applicable}	
• Investigator COI, CV, and training	
• VA Central IRB Form 108	
• VA Central IRB Form 108a	
• VA Central IRB Form 110 series	
• Protocol	
• Other vulnerable or special populations	
• FDA or Tissue Banking Issues	
Recruitment Materials	
• {List various recruitment materials to be discussed}	
•	
•	
•	
Privacy and Security	
1. PO Review and Certification Form	
2. ISO Review and Certification Form	
Informed Consent and HIPAA	
• {List informed consent document, any waiver requests, and HIPAA authorization form if applicable}	
•	
•	
Questionnaires and Surveys	
• {List investigator developed questionnaires and surveys – not commonly used tests or surveys}	
•	
Board Decision	
1. Motion for Board determination by Primary Reviewer	
2. List and Summary of Requested Modifications	
3. Has IRB approval criteria below been met?	
Approval Criteria	
• Risks to subject minimized?	
• Risks reasonable in relation to benefits?	
• Selection of subjects equitable?	

• IFC will be sought and appropriately documented?	
• Additional safeguards for vulnerable populations?	
• Data Safety and Monitoring Plan if required?	
• Privacy and Confidentiality protected?	
• COI managed? Investigators qualified?	
4. What is the continuing review period?	
6. Does medical record need to be flagged?	
7. Other Admin Comments:	
8. Call for a Second	
9. Vote Recorded	